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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/665,394
Filing Date: September 17, 2003
Appellant(s): GEISS, KURT-REINER

Paul Bianco
Reg. No. 43,500
For Appellant

EXAMINER'S ANSWER

1. This is in response to the appeal brief filed 05/17/10 appealing from the Office action mailed 10/14/09.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

Grounds of Rejection Withdrawn at Appeal

The rejections made under 35 USC 112.2 in the office action dated 10/14/09 have been withdrawn in light of applicant's arguments.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,514,973	Buchholz et al.	02-2003
US PG pub. 2003/0161861 A1	Lang et al.	08-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 14-15, 17-19 and 23-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchholz et al. (US Patent No. 6,514,973) in view of Lang et al. (US Pub. No. 2003/0161861 A1).

Buchholz et al. discloses that oral supplementation with 200 to 300 mg of phosphatidylserines per day for 2 to 6 months improves brain metabolism and benefits cognitive functions such as memory, thinking, learning, and the ability to concentrate especially in aging people and in patients with certain neurological and pathopsychological conditions (see column 2, lines 20-32).

The reference also discloses the effectiveness of phosphatidylserines in the treatment of senile dementia, Parkinson's disease epilepsy, depression, and age-associated memory impairment has also been demonstrated in several studies. (See column 2, lines 27-30). Buchholz et al. further teach that phosphatidyl serine provides metabolic support to a wide range of brain functions. Phosphatidyl serine stimulates glucose metabolism in the brain and also increases the number of neurotransmitter receptor sites. (See column 2, lines 32-35). Buchholz et al. discloses that the disclosed compound (which includes phosphatidyl serine) is suitable for food or food supplement composition (see column 6, lines 55-56). The invention also relates to food or food supplement compositions comprising one or more active ingredients according to claim 1. (It is to be noted that claim 1 comprises phosphatidyl serine).

The reference further discloses that food compositions comprise one or more active ingredients and one or more nutritional substances. The nutritional substances encompass all materials which are suited for consumption both by animals and/or by human beings, e.g. vitamins and provitamins thereof, fats, minerals or amino acids. Nutritional substances, which can be part of the inventive food compositions are e.g. materials, which are derived substantially from a single natural source such as sugar,

unsweetened juice, nectar or puree from a single species of plant, such as unsweetened apple juice (including a blend of different varieties of apple juice), grapefruit juice, orange juice, apple sauce, apricot nectar, tomato juice, tomato sauce, tomato puree, grain plants of a single species and materials produced from grain plants of a single species, such as corn syrup, rye flour, wheat flour or oat bran.

The food compositions are e.g. of food preparations such as breakfast foods, e.g. prepared cereals, toaster pastries, and breakfast drink mixes, infant formulas, dietary supplements, complete diet formulas, and weight-loss preparations, such as weight-loss drinks and weight-loss bars. The nutritional substances include all edible combinations of carbohydrates, lipids, proteins, inorganic elements, trace elements, vitamins, water, and active metabolites of plants and animals. (see column 5, lines 40-65 and column 6, lines 9-13). Buchholz et al. further teach that the specific dose o food or food supplement for each patient depends on a wide variety of factors, for example on the activity of the specific compounds employed, on the age, bodyweight, general state of health, sex, on the diet, the time and route of administration (see column 6, lines 45-50).

Although Buchholz et al. teach that phosphatidyl serine stimulates glucose metabolism in the brain and also increases the number of neurotransmitter receptor sites. (See column 2, lines 32-35), (thereby establishing relation of glucose with brain neural function), they do not explicitly teach role of carbohydrate in improving cognitive function of brain in a preferred embodiment or in an exemplified manner.

Lang et al. discloses a cereal product comprising starch, which improves cognitive performances, in particular memory retention, attention concentration, vigilance and /or mental well being in people and particularly in a child and an adolescent. Table 1 on page 2 discloses a composition comprising spaghetti, kidney beans potatoes white bread and whole meal bread etc. Table 8 depicts carbohydrates, proteins and lipids. In paragraph [0019], Lang clearly teaches that cereal products in particular biscuits and or crackers with digestible starch content greater from about 12 to 20% amount improve the mental well-being and /or cognitive performances in particular memorization, attention, concentration and/or vigilance in person, the reference further emphasizes in paragraph [0022] on page 1 that slowly available glucose content is the preferred carbohydrate that can be used.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate carbohydrates in the reference of Buchholz et al. since Lang et al. teach that food products containing carbohydrates such as starch improve cognitive performances. One skilled in the art would have been motivated to incorporate starch in the teachings of Buchholz because Buchholz teaches that Phosphatidyl serine stimulates glucose metabolism in the brain and also increases the number of neurotransmitter receptor sites. (See column 2, lines 32-35) and Lang et al. teaches that starch improves cognitive performances. Since starch is known to breakdown into glucose during metabolism, one skilled in the art would have reasonable expectation of success in combining starch as taught by Lang et al. and phosphatidylserine as taught by Buchholz et al. in improving cognitive performances

because Lang explicitly teaches increasing concentration, attention and memory due to carbohydrates and Buchholz teaches cognitive performance enhancement due to phosphatidylserine. As such combination of the two known ingredients known to improve the cognitive performance would have resulted predictable results.

With respect to various amounts and percentages of various components, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time the invention was made by doing experimental manipulations.

(3) Response to Argument

Appellant argues for composition claims and for method claims on pages 14-24 and 25-28 respectively of appeal brief filed that the combination of Buchholz and Lang does not disclose every feature of the composition as claimed and combination of Buchholz and Lang would not produce the composition as claimed; and the prior art provides no reasonable basis for suggestion or motivation to combine the teachings of Buchholz and Lang.

Appellant's arguments are not persuasive because Buchholz teaches phosphatidyl serine increases glucose metabolism and secondary reference teaches starch in improving cognitive performances. While it is true that the instant claims do not recite the limitation of increasing glucose metabolism in brain however, by this teaching one of ordinary skill would envisage use of starch in cerebral activity. Regarding Lang's

teachings, it is the position of the Examiner that Lang explicitly teaches improvement in cognitive performances; as such one of ordinary skill would have envisaged utilizing both phosphatidylserine and carbohydrate for cognitive performances. Therefore the assertion that no obviousness exists in the rejections as cited is not well taken.

Appellant argues that Lang provides a more complex view of the effects of carbohydrates on cognitive function. Lang does not disclose that foods merely containing "starch" or "carbohydrates" are capable of improving cognitive function, but rather discloses a cereal product, having a specific ratio of slowly-digestible starch to total starch content, which is capable of improving cognitive function (emphasis added by Appellant). The positive effects are due to the choice of appropriate ratio and not simply from an inclusion of carbohydrates. Appellant adds that it is clearly evident in the experimental examples of Lang wherein he tested his food product against ready-to-eat cereals (Example 1) that also contained carbohydrates, but did not improve cognitive functions, neither the cited patent documents (Buchholz and Lang) nor any other prior art discloses a composition including a synergistically-interacting combination of phosphatidyl serine and carbohydrates which improves cognitive functional capacity. Thus according to appellant, the combination of Buchholz and Lang can not be said to disclose every feature of the composition as claimed and thus would not produce the composition as claimed. Appellants further argues on pages 17 and 20 that all types of carbohydrates are not equivalent nor are they metabolized in the same manner upon consumption; *i.e.* each type produces different fluctuations in blood glucose levels. This

fluctuation is measured by the glycemic index (GI). Many people who are weight-conscious and/or suffer from diabetes benefit from a diet consisting of food having a low glycemic index. Appellant adds that considering the numbers of people suffering from this condition(s), even a quick internet search provides much information regarding the differences among carbohydrate foods. Appellant then refers to the attached Evidence Exhibit H, accessed from the Official website of the Glycemic Index and GI Database, which lists the glycemic index of many foods and provides advice for people switching to a low GI diet. Many simple carbohydrates have a high glycemic index and are quickly digested. Conversely, some starches have lower glycemic indexes and are slowly digested. Appellant further argues that all carbohydrates can not be used interchangeably to provide the same effects upon consumption. Therefore, the starch of Lang is not an obvious substitute for the carbohydrate of the claimed composition (food/food bar).

Appellant's arguments are not persuasive because as admitted by Appellants, Lang teaches starch and carbohydrates are capable of improving cognitive function. Instant claims recite the limitations which include carbohydrates in a food bar for improving cognitive functions, the instant claims do not provide breakdown of carbohydrates, therefore by giving broadest reasonable interpretation to claims, it is respectfully pointed out that prior art's slowly -digestible starch which is capable of improving cognitive function cannot be excluded from being read into claims. Besides in paragraph [0019], Lang clearly teaches that cereal products in particular biscuits and or crackers with digestible starch content greater from about 12 to 20% amount improve

the mental well-being and /or cognitive performances in particular memorization, attention, concentration and/or vigilance in person, the reference further emphasizes in paragraph [0022] on page 1 that slowly available **glucose content** is the preferred carbohydrate that can be used. It is respectfully pointed out that instant claims 17, 26 and 34 disclose glucose as one of the carbohydrates listed among several others in Markush group. Therefore if appellant themselves claim and argue carbohydrate such as **glucose** to provide cognitive performance, it is unclear to the examiner how the glucose taught by the prior art Lang, will not produce the same effect as claimed and argued by appellants. Lang further discloses in paragraph [0024] on page 2 that 2 to 40 g per 100 g of sugar is used in the cereal product wherein the sugar is in particular **monosaccharide and or disaccharide such as glucose, sucrose, fructose and or** maltose. The Examiner respectfully points to the board that appellants themselves claim carbohydrates such as glucose, fructose and sucrose in instant claim 17, 26 and 36 and generically claim carbohydrate in instant claim, 14, 23 and 43. Since Lang teaches utilization of the claimed carbohydrates in substantially similar claimed amount for the same claimed cognitive improvement (see [0019], [0020], [0022], [0029] learning memorization, attention and concentration etc.) and Buchholz teaches improvement of cognitive performance due to phosphatidylserine, one of ordinary would have envisaged utilizing the two components together for cognitive function improvements.

Appellants argues on page 17 in paragraphs 4-5 that Lang discloses conflicting results regarding levels of glucose and improvement in cognitive functions and there exist many prior art which provide contradictory evidence that phosphatidylserine and

carbohydrate demonstrated improvement in cognitive functions, Appellant then refers to phosphatidylserine which they contend show unpredictability in providing synergistic interaction between phosphatidylserine and carbohydrate in improving cognitive functions.

Appellant's arguments are not persuasive because various results from previous experimentations which either demonstrate improvement or do not demonstrate improvement do not **negate the** fact taught by Buchholz and Lang which provide teachings that phosphatidylserine and carbohydrates improve cognitive functions respectively as discussed above. Besides, appellants have not substantiated the argued unpredictability in results of improvements of cognitive performances by comparing various existing data with scientific and quantitative experiments.

Appellant argues that in Example 1, Lang compares the effects of his composition (biscuits) and commercial ready-to-eat cereals on learning in rats. Although no particular ready-to-eat cereal is identified, the high sugar content of cereals, especially those made for children, is very well known. The results of the comparison showed that the consumption of biscuit is followed by learning which is significantly superior to that following the consumption of cereals. *See* paragraph [0071] and Figures 1 and 2 of Lang. The results of Lang contradict the results of the invention, i.e. by demonstrating that foods containing high amounts of simple sugars decrease cognitive function. Appellant adds that Lang's results further negate any apparent reason to combine. Appellants add that considering that Lang discloses a food having an effect

opposite the effect of the claimed composition, Lang can be considered as teaching away from the claimed composition. *See* MPEP 2141.02 VI.

Appellant's arguments are not persuasive because preferred examples and other embodiments of a reference do not constitute teaching away. The reference is considered good for what it teaches and as discussed above Lang explicitly teaches cognitive function improvement by utilizing the claimed carbohydrates and thus combination of carbohydrate with phosphatidylserine of Buchholz would have been with in purview of skilled artisan. Nowhere in Lang is it stated that carbohydrates do not improve cognitive performance.

Appellant argues that the declarations under 37 C.F.R. § 1.132 submitted and filed on December 19, 2008 (Evidence Exhibit C) and June 12, 2009 (Evidence Exhibit D), shows a synergistic effect on cognitive functional capacity from the combination of phosphatidyl serine and carbohydrates over the effect of each ingredient alone (i. e. phosphatidyl serine alone and carbohydrates alone). Thus, this data constitutes objective evidence of non-obviousness of the claimed composition (food/food bar). The effect of the combination of phosphatidyl serine and carbohydrates on concentration, memory, and attention while playing Golf is demonstrated in the first experimental example provided in both Declarations. In this experiment, improvements in concentration, memory, and attention were observed in the subjects after twelve weeks of consuming the bars, i.e. the claimed composition, and further the improvements were observed to decline after the subjects stopped consuming the bars. The study

volunteers were evaluated pre-supplementation and after twelve weeks of consuming one IQPLUS Brain Bar per day for the first two weeks, followed by half an IQPLUS Brain Bar for the next ten weeks. The IQPLUS Brain Bar contains 200 mg of phosphatidyl serine and 20 g of carbohydrates. After the second evaluation, the volunteers stopped consuming the IQPLUS Brain Bars and were re-evaluated during week twenty-four. The combination of phosphatidyl serine and carbohydrates in the form of the IQPLUS Brain Bar resulted in improvements in all categories of concentration, attention, and memory tested (results after twelve weeks of IQPLUS Brain Bar consumption in comparison to starting values). A comparison of results after twelve weeks consumption with results after an additional twelve weeks without any further supplementation showed a decline in all categories at week twenty-four. The results regarding concentration and attention are shown in Table 2 and results regarding memory and attention are shown in Table 3 (Declaration, experimental example one). Appellants further disclose their results in light of performance of golf swing which requires certain level of cognition and disclose in detail in pages 21-28, how they achieved synergistically significant result with a food bar comprising phosphatidylserine and carbohydrate.

In response to appellant's evidence regarding synergistic interaction of phosphatidylserine and carbohydrate in improving cognitive functional capacity in the declaration provided, it is the position of the examiner that the declaration which has been submitted to provide synergistic results is insufficient to overcome the

obviousness rejection. As pointed out earlier the declaration under 37 CFR 1.132 filed on 05/17/10 or earlier is insufficient to overcome the rejection of claims and thus does not overcome the rejections as set forth in the last Office action because:

First, appellants contend unexpected results with simple carbohydrates but the claims as recited do not recite the limitation of being simple, Claim 1 generically recites carbohydrates and does not recite which specific carbohydrate is used in the food bar. Additionally, the declaration provides data for only 200 mg of phosphatidyl serine and 20 g of carbohydrate and for 150 mg PS and 15 mg of carbohydrates whereas the claims as recited has the limitation of minimum of 100 mg of phosphatidyl serine and minimum of 10 g of carbohydrate, as such no data has been provided for amounts which are below 150 mg of phosphatidyl serine and less than 15 g of carbohydrate. Thus the declaration does not commensurate with the scope of the claims.

The declaration does not provide any cognitive performance for amount such as 100 mg of phosphatidyl serine or 10 g of carbohydrate. Furthermore, carbohydrate is a very broad generic term which encompasses starches of various glycemic indexes. One of ordinary skill would expect varying extent of cognitive performance due to different carbohydrates with varied glycemic index. Applicants have only provided results with generic carbohydrate with no mention of any specific component with specific glycemic index such as glucose, fructose etc. that are claimed. As such the scope of claims 14, 26, 34 and 43 does not commensurate with the scope of declaration or the unexpected results provided.

Review of the graph on page 7, appendix C of the declaration shows standard deviation which is so high that one cannot determine the statistical significance, let alone **the palatable significance**. From the graph it is concluded that the results do not appear to show even **an additive effect**. The improvement in cognitive performance is not to an unexpected degree.

Appellants have provided experimental data on page 2 of appendix C by comparing results of subjects who consumed the IQPLUS bar and subjects **who did not consume the IQPLUS bar for** showing improvement in concentration/attention, memory and attention. This is not statistically significant comparison, appellants have not compared and provided experimental results or experimental data (i.e. no. of experiments, mean, and standard deviation of the mean or analyses of experiment) to show (concentration/attention, memory and attention) for subjects who consumed carbohydrate itself or phosphatidylserine itself. There is no comparison of statistical results provided for subjects who consumed IQPLUS bar with subjects who consumed food bar comprising only carbohydrate or a food bar comprising phosphatidylserine itself. Thus the experimental data as provided is insufficient to provide statistically significant results. Additionally, the section under results on pages 6- 7 of appendix C shows difference in no. of subjects who consumed PS and carbohydrates. Results from only **2 subjects consuming PS do not provide any statistical significance.** The rationale behind having 10 subjects consuming carbohydrate and only **2 subjects** consuming PS is not clear to the Examiner (see page 6). Appellants contend that the declaration recognizes synergistic effect of PS and carbohydrate, however there is no

Control to compare with. The results disclosed on page 3 of appendix C attest applicants own invention, however the results are obvious in view of the teachings of prior art because Buchholz teaches cognitive improvement due to PS and Lang teaches due to carbohydrate. Instant claims recite the minimum effective amount for improving cognitive performance to be 100 mg, the declaration on page 6 and 7, recognizes that there is no difference in results in pre and post tests when only phosphatidylserine or only carbohydrate was consumed, it is unclear to the Examiner as to how a nutritional bar with 100 mg PS will improve cognitive performance when the one with 200mg PS, does not show any difference in cognitive performance compared to one without any PS.

Appellants arguments with respect to method claims cited on pages 24-28 are same as that of composition claims, since the rejection entails teachings of Buchholz and Lang together for all the instant claims that is composition claims and method claims, the response as presented above addressees all the arguments of appellants which are basically same as that of composition claims argued above. Regarding synergistic results argued by appellants as presented by Appellants in the declaration, the examiner refers to the response presented above in detail which discloses that declaration is insufficient in providing experimental results of statistical significance because the improvement in cognitive performance (attention. Memory, concentration) is compared with subjects consuming the IQPLUS bar (with phosphatidylserine and carbohydrate) and subjects **who did not consume** the bar, however, no experimental data of statistical significance (no. of experiments performed with mean and standard

deviation) has been compared or provided for subjects who consumed only phosphatidylserine or only carbohydrate (refer to appendix C, pages 2-3). Additionally, the graph on page 6 of appendix C shows very high standard deviation which makes the results speculative in examiners opinion. Furthermore, according to instant claims the cognitive function capacity includes memory, attention and concentration, the results shown by appellants by performing experiments on Golf swing and teeing off on page 4-6 of appendix C has nothing to do with memory, it only deals with attention and concentration and as pointed out above, the results shown on the graph on page 7 do not even show additive effect by consuming phosphatidylserine and carbohydrate.

In light of the above, it is the position of the examiner that the declaration is insufficient to overcome the rejection and also does not commensurate with the scope of the claims because through out the declaration, results are presented with carbohydrates generically and no specific results are provided for glucose, fructose etc. which are claimed in instant claims especially in light of appellants arguments' while rebutting Lang's teachings by saying that every carbohydrate is not same and has different glycemic index therefore Lang's carbohydrate is different from the claimed one. If such is the case then appellant's declaration with generic carbohydrate is also insufficient within the meaning of full scope.

(4) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Snigdha Maewall/

Examiner, Art Unit 1612

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